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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John S. Lollar

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/813,507	<b>Applicant(s)</b> LOLLAR, JOHN S.	
	<b>Examiner</b> TERRA C. GIBBS	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2009 and 22 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-18 and 41-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Office Action is a response to Applicant's Election filed February 26, 2009 and Applicant's Amendment and Remarks filed September 22, 2008.

Claims 1-26 and 41-43 are pending in the instant application.

This application contains claims 1-4 and 19-26 drawn to an invention nonelected with traverse in the reply filed on October 13, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Accordingly, claims 5-18 and 41-43 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

Applicant's election with traverse of the K1245R mutation from claims 41-43 in the Election filed February 26, 2009 is acknowledged. **Applicant's traversal is moot** in view of the Amendment filed February 26, 2009. Specifically, the traversal is moot in view of Applicant's Amendment to the claims to remove recitation of mutations R503A, R508A, P511A, K1155E, T1158A, H116R, E1201D, F1203H, K1220M, K1246N, T1249S, S1267A, and I1280V.

***Claim Rejections - 35 USC § 102***

In the previous Office Action mailed March 25, 2008, claims 5-18 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,859,204. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed March 25, 2008.

***Response to Arguments***

In response to this rejection, Applicants argue that the '204 patent fails to disclose the features claimed by Applicant. First, Applicants argue that the '204 patent does not disclose nor characterize the expression of SEQ ID NO:38. Applicants remind the Examiner that the instant claims recite that the polypeptide is characterized by high-level expression.

This argument has been fully considered, but is not found persuasive because the '204 patent discloses throughout the specification the expression of a factor VIII polypeptide. The '204 even goes as far as to disclose expression systems in the form of vectors and plasmids that can be used to express the factor VIII polypeptides of their invention.

Second, Applicant's argue that SEQ ID NO:38 as disclosed by the '204 patent is not an isolated nucleic acid molecule comprising a nucleotide sequence having at least 95% sequence identity to a polynucleotide shown in SEQ ID NO:18 as now claimed. Applicants argue that SEQ ID NO:38 is instead less than 87% identical to SEQ ID NO:18 of Applicant's invention.

This argument has been considered, but is not found persuasive because the issue is that the claims are drawn to:

“An isolated nucleic acid molecule encoding a modified factor VIII polypeptide comprising **a** nucleotide sequence having at least 95% identity to **a** polynucleotide sequence shown in SEQ ID NO:18”.

This claim encompasses nucleic acids that comprise the full-length sequence of SEQ ID NO:18, or any portion of SEQ ID NO:18. Applicant is reminded that during patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See MPEP § 2111-2116.01. Given its broadest reasonable interpretation, claim 1 is anticipated by any dinucleotide or larger oligonucleotide, so long as the dinucleotide has at least 95% identity to a polynucleotide sequence shown in SEQ ID NO:18. It should be noted that replacement of the term "a" (shown in bold above) with the term "the" in the claims would obviate the instant rejection.

In this regard, the rejection against claims 5-18 as being anticipated by U.S. Patent No. 5,859,204 is maintained.

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In the previous Office Action mailed March 25, 2008, claims 5-18 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,458,563. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed March 25, 2008.

### ***Response to Arguments***

In response to this rejection, Applicants argue that the '563 patent fails to disclose the features claimed by Applicant. First, Applicants argue that the '563 patent does not disclose nor characterize the expression of SEQ ID NO:37. Applicants remind the Examiner that the instant claims recite that the polypeptide is characterized by high-level expression.

This argument has been fully considered, but is not found persuasive because the '563 patent discloses SEQ ID NO:37 is POL1212, a partially B-domainless porcine factor VIII. The '563 patent also discloses at Example 6, the expression of active, recombinant B-domainless factor VIII. Furthermore, the '563 patent throughout the specification discloses the expression of a factor VIII polypeptide. In fact, the '563 patent explicitly discloses:

“The materials, genetic structures, host cells and conditions which permit expression of a given DNA sequence to occur are well-known in the art”

The '563 even goes as far as to disclose expression systems in the form of vectors and plasmids that can be used to express the factor VIII polypeptides of their invention.

Second, Applicant's argue that SEQ ID NO:37 as disclosed by the '563 patent is not an isolated nucleic acid molecule comprising a nucleotide sequence having at least 95% sequence identity to a polynucleotide shown in SEQ ID NO:18 as now claimed. Applicants argue that SEQ ID NO:37 is instead less than 90.5% identical to SEQ ID NO:18 of Applicant's invention.

This argument has been considered, but is not found persuasive because as discussed *supra*, the issue is that the claims are drawn to:

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“An isolated nucleic acid molecule encoding a modified factor VIII polypeptide comprising **a** nucleotide sequence having at least 95% identity to **a** polynucleotide sequence shown in SEQ ID NO:18”.

This claim encompasses nucleic acids that comprise the full-length sequence of SEQ ID NO:18, or any portion of SEQ ID NO:18. Applicant is reminded that during patent examination, the claims are given the broadest reasonable interpretation consistent with the specification. See MPEP § 2111-2116.01. As discussed *supra*, given its broadest reasonable interpretation, claim 1 is anticipated by any dinucleotide or larger oligonucleotide, so long as the dinucleotide has at least 95% identity to a polynucleotide sequence shown in SEQ ID NO:18. It should be noted that replacement of the term "a" (shown in bold above) with the term "the" in the claims would obviate the instant rejection.

In this regard, the rejection against claims 5-18 as being anticipated by U.S. Patent No. 6,458,563 is maintained.

Applicant's Amendment filed September 22, 2008 necessitated the new ground(s) of rejection presented below:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 41-43 are drawn to an isolated nucleic acid molecule encoding a modified factor VIII polypeptide comprising a nucleotide sequence having at least 95% identity to a polynucleotide sequence shown in SEQ ID NO:18, wherein said nucleotide sequence encodes a polypeptide characterized by high-level expression when compared to a corresponding human factor VIII polypeptide expressed under the same conditions, and wherein the isolated nucleic acid further comprises the mutation K1245R.

The limitation, “wherein the isolated nucleic acid further comprises the mutation K1245R” was first introduced in the amendment to the claims filed September 22, 2008. The Amendment filed September 22, 2008 does not indicate where support for the new limitation is found. A review of the specification does not reveal support for the limitation either. In this regard, the limitation, “wherein the isolated nucleic acid further comprises the mutation K1245R” does not appear to be supported in Applicant’s disclosure and is therefore new matter. Should Applicant disagree, Applicant is encouraged to point out, with particularity, by page and line number where such support might exist.

Applicants are required to cancel the new matter in the reply to this Office Action.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 6, 2009  
/Terra Cotta Gibbs/

**/Sean R McGarry/**

**Primary Examiner, Art Unit 1635**